

We claim:

1. A method of preparing a cell concentrate, comprising the steps of:
  - providing a physiological solution not previously subjected to centrifugation;
  - subjecting said physiological solution to a filter to produce a filter retentate and a permeate solution, wherein said filter retentate comprises platelets, nucleated cells, or both per unit volume greater than in the physiological solution and wherein said permeate solution comprises plasma and red blood cells; and
  - removing the filter retentate from the filter.
2. The method of claim 1, wherein the physiological solution comprises bone marrow aspirate, blood, or a mixture thereof.
3. The method of claim 1, wherein said nucleated cells comprise leukocytes, stem cells, connective tissue progenitor cells, osteoprogenitor cells, chondroprogenitor cells, or a mixture thereof.
4. The method of claim 1, wherein the stem cells are mesenchymal stem cells, hematopoietic stem cells, or both.
5. The method of claim 1, wherein the providing step comprises combining an additional solution with the physiological solution.
6. The method of claim 5, wherein the additional solution is water.
7. The method of claim 5, wherein the additional solution is a hypotonic solution.
8. The method of claim 5, wherein the additional solution is a hypotonic solution comprising sodium chloride.
9. The method of claim 1, further comprising delivering the filter retentate removed from the filter to a bone defect in an individual.
10. The method of claim 1, wherein said method further comprises the step of admixing a scaffold material to the filter retentate removed from the filter to produce a scaffold material/filter retentate mixture.
11. The method of claim 10, further comprising the step of delivering the scaffold material/filter retentate mixture to a bone defect in an individual.
12. The method of claim 10, wherein the scaffold material is comprised of a block, paste, dust, cement, powder, granule, putty, liquid, gel, solid, or a mixture thereof.
13. The method of claim 10, wherein the scaffold material is comprised of a ceramic, a polymer, a metal, allograft bone, autograft bone, demineralized bone matrix, or a mixture thereof.

14. The method of claim 10, wherein the scaffold material is biodegradable.
15. The method of claim 10, wherein the scaffold material is osteoconductive, osteogenic, osteoinductive, or a combination thereof.
16. The method of claim 10, wherein the scaffold material is comprised of synthetic material, natural material, or a combination thereof.
17. The method of claim 10, said method further comprising the step of admixing a biological agent with the filter retentate removed from the filter, the scaffold material, or a combination thereof.
18. The method of claim 17, wherein the biological agent admixed with the scaffold material is further defined as the biological agent being comprised on the scaffold material, in the scaffold material, or both.
19. The method of claim 10, further comprising the step of admixing a clotting initiator with the second product, the scaffold material, or both.
20. The method of claim 1, wherein the filter retentate removed from the filter is subjected to at least one further processing step.
21. A method of preparing a cell concentrate comprising a number of nucleated cells, platelets, or both per unit volume greater than in the physiological solution, comprising the steps of:
  - providing a physiological solution;
  - subjecting said physiological solution to a first filtration device to isolate nucleated cells, platelets, or both from said physiological solution, said isolating step producing a first product; and
  - subjecting said first product to a second filtration device to produce a second product.
22. The method of claim 21, wherein the first filtration device is a nucleated cell filtration device.
23. The method of claim 22, wherein the nucleated cell filtration device is further defined as a leukocyte reduction filtration device.
24. The method of claim 21, wherein the second filtration device is further defined as a hollow fiber filtration device.
25. The method of claim 24, wherein the device comprises a pore size between about 0.05  $\mu\text{m}$  and about 5  $\mu\text{m}$ .

26. The method of claim 25, wherein the device comprises a pore size between about 0.2  $\mu\text{m}$  and about 0.5  $\mu\text{m}$ .
27. The method of claim 21, wherein said method lacks a centrifugation step.
28. The method of claim 21, wherein the physiological solution comprises bone marrow aspirate, blood, or a mixture thereof.
29. The method of claim 1, wherein said nucleated cells comprise leukocytes, stem cells, connective tissue progenitor cells, osteoprogenitor cells, chondroprogenitor cells, or a mixture thereof.
30. The method of claim 29, wherein the stem cells are mesenchymal stem cells, hematopoietic stem cells, or both.
31. The method of claim 21, wherein the providing step comprises combining an additional solution with the physiological solution.
32. The method of claim 31, wherein the additional solution is water.
33. The method of claim 31, wherein the additional solution is a hypotonic solution.
34. The method of claim 31, wherein the additional solution is a hypotonic solution comprising sodium chloride.
35. The method of claim 21, wherein said method further comprises the step of delivering the second product to a bone defect in an individual.
36. The method of claim 21, wherein said method further comprises the step of admixing a scaffold material to said second product to produce a scaffold material/second product mixture.
37. The method of claim 36, further comprising the step of delivering the scaffold material/second product mixture to a bone defect in an individual.
38. The method of claim 36, wherein the scaffold material is comprised of a block, paste, dust, cement, powder, granule, putty, liquid, gel, solid, or a mixture thereof.
39. The method of claim 36, wherein the scaffold material is comprised of a ceramic, a polymer, a metal, allograft bone, autograft bone, demineralized bone matrix, or a mixture thereof.
40. The method of claim 36, wherein the scaffold material is biodegradable.
41. The method of claim 36, wherein the scaffold material is osteoconductive, osteogenic, osteoinductive, or a combination thereof.
42. The method of claim 36, wherein the scaffold material is comprised of synthetic material, natural material, or a combination thereof.

43. The method of claim 36, said method further comprising the step of admixing a biological agent with the second product, the scaffold material, or a combination thereof.
44. The method of claim 43, wherein the biological agent admixed with the scaffold material is further defined as the biological agent being comprised on the scaffold material, in the scaffold material, or both.
45. The method of claim 21, further comprising the step of admixing a clotting initiator with the second product, the scaffold material, or both.
46. The method of claim 21, wherein said method further comprises the step of subjecting the physiological solution to a fat reducing step.
47. The method of claim 46, wherein the form of said fat is cellular or non-cellular.
48. The method of claim 46, wherein said fat reducing step comprises subjecting said physiological solution to a fat cell reduction filter.
49. The second product generated by the method of claim 21.
50. A method of increasing nucleated cell concentration and/or platelet concentration from a physiological solution, comprising the steps of:
  - providing a physiological solution;
  - subjecting said physiological solution to a nucleated cell filtration device to isolate nucleated cells, platelets, or both from said physiological solution, said isolating step producing a first product; and
  - subjecting said first product to another filtration device to produce a second product, said second product comprising a number of nucleated cells, platelets, or both per unit volume greater than in the physiological solution.
51. The method of claim 50, wherein the method lacks a centrifugation step.
52. The method of claim 50, wherein said physiological solution comprises bone marrow aspirate, blood, or a mixture thereof.
53. The method of claim 50, wherein the providing step comprises combining an additional solution with the physiological solution.
54. The method of claim 53, wherein the additional solution is water.
55. The method of claim 53, wherein the additional solution is a hypotonic solution.
56. The method of claim 53, wherein the additional solution is a hypotonic solution comprising sodium chloride.

57. The method of claim 50, wherein said providing the bone marrow aspirate step is further defined as aspirating the bone marrow from an individual into a first syringe to produce a bone marrow aspirate.
58. The method of claim 57, wherein the first syringe comprises an anti-coagulant, an isotonic solution, or both.
59. The method of claim 57, wherein the subjecting the bone marrow aspirate to a nucleated cell filtration device is further defined as:
  - introducing the bone marrow aspirate to a first housing device, said first housing device connected in-line to a leukocyte reduction filter and said leukocyte reduction filter connected in-line to a second housing device, wherein the leukocyte filter permits passage of plasma and red blood cells through said filter but inhibits passage of nucleated cells, platelets, or both;
  - introducing a purge solution to the filter to produce a purge solution/nucleated cell/platelet mixture; and
  - retrieving the purge solution/nucleated cell/platelet mixture from said filter.
60. The method of claim 50, wherein said subjecting the first product to a filtration device comprises subjecting the first product to a hollow fiber filtration device.
61. The method of claim 50, wherein said subjecting the first product to a filtration device comprises subjecting the first product to a filtration device that comprises a filter, and wherein the feed direction of the first product through said filtration device is nonparallel to the flow of the first product across a membrane.
62. The method of claim 50, wherein said subjecting the first product to a filtration device comprises subjecting the first product to a filtration device that comprises a filter, wherein the feed direction of the first product through said filtration device is parallel to the flow of the first product across the filter.
63. The method of claim 50, wherein there is substantially no recirculation of the first product.
64. The method of claim 50, wherein said nucleated cell filtration device comprises a filter and substantially the majority of the first product passes across the filter once.
65. The method of claim 61, wherein said device comprises a filter and substantially the majority of the first product passes across the filter more than once.
66. The method of claim 52, wherein the providing the blood step is further defined as aspirating the blood from an individual into a first syringe to produce a blood aspirate.

67. The method of claim 66, wherein the first syringe comprises an anti-coagulant, an isotonic solution, or both.

68. The method of claim 66, wherein the subjecting the blood aspirate to a nucleated cell filtration device is further defined as:

introducing the blood aspirate to a first housing device, said first housing device connected in-line to a leukocyte reduction filter and said leukocyte reduction filter connected in-line to a second housing device, wherein the leukocyte filter permits passage of plasma and red blood cells through said filter but inhibits passage of nucleated cells, platelets, or both;

introducing a purge solution to the filter to produce a purge solution/nucleated cell/platelet mixture; and

retrieving the purge solution/nucleated cell/platelet mixture from said filter.

69. The method of claim 52, wherein the providing the bone marrow aspirate/blood mixture step is further defined as aspirating the bone marrow and blood from an individual into a first syringe to produce a bone marrow aspirate/blood aspirate.

70. The method of claim 69, wherein the first syringe comprises an anti-coagulant, an isotonic solution, or both.

71. The method of claim 52, wherein the subjecting the bone marrow aspirate/blood aspirate to a nucleated cell filtration device is further defined as:

introducing the bone marrow aspirate/blood aspirate to a first housing device, said first housing device connected in-line to a leukocyte reduction filter and said leukocyte reduction filter connected in-line to a second housing device, wherein the leukocyte filter permits passage of plasma and red blood cells through said filter but inhibits passage of nucleated cells, platelets, or both;

introducing a purge solution to the filter to produce a purge solution/nucleated cell/platelet mixture; and

retrieving the purge solution/nucleated cell/platelet mixture from said filter.

72. The method of claim 50, wherein said method further comprises the step of subjecting the physiological solution to a fat reducing step.

73. The method of claim 72, wherein said fat reducing step comprises subjecting said physiological solution to a fat reduction filter.

74. A method of treating a bone defect in an individual, comprising the steps of:

obtaining a physiological solution comprising nucleated cells, platelets, or both;

subjecting the physiological solution to a nucleated cell-filtration device to isolate nucleated cells, platelets, or both, said isolating step producing a first product;

subjecting the first product to a hollow fiber filtration device to produce a second product, said second product comprising a number of nucleated cells, platelets, or both per unit volume greater than in the physiological solution; and

delivering the second product to the bone defect in the individual.

75. The method of claim 74, wherein the method lacks a centrifugation step.
76. The method of claim 74, wherein the bone defect comprises a break, fracture, void, diseased bone, loss of bone, brittle bone, weak bone, bone injury, or bone degeneration.
77. The method of claim 74, wherein the method further comprises the step of admixing a scaffold material with said second product.
78. The method of claim 74, wherein said physiological solution is blood, bone marrow aspirate, or a mixture thereof.
79. The method of claim 74, wherein said physiological solution is obtained from said individual.
80. The method of claim 74, wherein said method occurs in a hospital facility or a health care provider facility.
81. The method of claim 74, wherein the method further comprises administering to the individual an additional bone defect therapy.
82. The method of claim 81, wherein said additional bone defect therapy comprises fracture repair, surgery, bone excision, implant delivery, external stimulation, or a combination thereof.
83. The method of claim 74, wherein said nucleated cells comprise stem cells, connective tissue progenitor cells, osteoprogenitor cells, chondroprogenitor cells, or a mixture thereof.
84. The method of claim 83, wherein said stem cells are mesenchymal stem cells, hematopoietic stem cells, or a mixture thereof.
85. The method of claim 74, wherein said delivering the second product to the individual comprises applying the second concentrated product directly to the bone defect.
86. The method of claim 85, wherein the applying is with a scoop, scoopula, syringe, rod, tube, or spatula.

87. The method of claim 74, said method further comprising the step of admixing a biological agent with the second product, the scaffold material, or a combination thereof.
88. The method of claim 87, wherein the biological agent admixed with the scaffold material is further defined as the biological agent being comprised on the scaffold material, in the scaffold material, or both.
89. The method of claim 74, wherein said method further comprises the step of subjecting the physiological solution to a fat reducing step.
90. The method of claim 74, wherein said fat reducing step comprises subjecting said physiological solution to a fat reduction filter.
91. A method of preparing an osteogenic cell concentrate from a physiological solution comprising subjecting the physiological solution to two filtration steps.
92. The method of claim 91, wherein said method lacks centrifugation.
93. A kit for preparing a cell concentrate, comprising a first filtration device and a second filtration device, both of which are housed in a suitable container.
94. The kit of claim 93, wherein the first filtration device is a nucleated cell filtration device.
95. The kit of claim 93, wherein the second filtration device is a microfiltration device.
96. The kit of claim 95, wherein the microfiltration device is further defined as a hollow fiber filtration device.
97. The kit of claim 93, wherein said kit further comprises a scaffold material housed in a suitable container.
98. The kit of claim 93, wherein said kit further comprises a biological agent housed in a suitable container.
99. A kit for treating a bone defect, comprising a plurality of cells housed in a suitable container, wherein said cells are nucleated cells, platelets, or both.
100. The kit of claim 99, wherein said kit further comprises a scaffold material housed in a suitable container.
101. The kit of claim 99, wherein said kit further comprises a biological agent housed in a suitable container.
102. A method of preparing a cell concentrate, comprising the steps of:  
providing a physiological solution not previously subjected to centrifugation;



subjecting said physiological solution to a leukocyte reduction filter to produce a filter retentate and a permeate solution, wherein said filter retentate comprises platelets, nucleated cells, or both per unit volume greater than in the physiological solution and wherein said permeate solution comprises plasma and red blood cells; and

removing the filter retentate from the filter.